

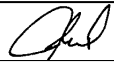


Document History:

**Title: Receipt of Plasma Protein Products
(Derivatives)**

Site(s): All DSM sites

Document #:	160-INV-07c	Version #:	02
Section:	Manitoba Transfusion Quality Manual for Blood Banks	Subsection:	INV Module

Approved by: <u>C Musuka</u>	Written By: <u>TM Discipline Team</u>
Signature: 	
Date: <u>31-JAN-2017</u>	Date: <u>March 2011</u>

#	Details of Revisions:	Approval:	Date:
1	<ul style="list-style-type: none"> • Document # changed from 160-INV-10 to 160-INV-07c. • The changes described below reflect the changes from 160-INV-10 V02 to new document # 160-INV-07c V01. • 4.1.6.1 added bullet to notify ward if applicable • 5.6 new for patient specific units • 6.3 first note revised Trace Line procedures to refer to 	C Musuka	18-APR-2013
2	<ul style="list-style-type: none"> • Revised throughout to Plasma Protein products (Derivatives) • 4.0 revised throughout to update with current process • 5.0 revised to reflect changes in 4.0 • 6.3 revised with current process • 6.5 new 	C Musuka	31-Jan-2017
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Receipt of Plasma Protein Products (Derivatives)

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1.0 Principle

Refer to INV Procedure- Receiving Blood, Blood Components and Plasma Protein Products (Derivatives)

2.0 Scope and Related Policies

Refer to INV Procedure- Receiving Blood, Blood Components and Plasma Protein Products (Derivatives)

3.0 Materials

Refer to INV Procedure- Receiving Blood, Blood Components and Plasma Protein Products (Derivatives)

4.0 Procedure

Note: For Trace Line Sites refer to Trace Line Procedures:

- *Receipt of Blood, Blood Components and Plasma Protein Products- Derivatives (from CBS) in Trace Line*
- *Handling in Trace Line: Receipt of Inter-Facility Shipment of Blood, Blood Components and Derivatives*

4.1 Ensure there is a security seal on the shipping box.

4.1.1 If a security seal is not present:

- contact the shipper immediately, quarantine the product while investigated. Refer to procedural notes 6.1 and 6.3.
- If the box was transported with a patient and there is no documentation indicating the box was opened en route by authorized personnel; then contact the shipper immediately, quarantine the product while investigated. Refer to procedural note 6.4

4.2 Remove security seal, obtain packing slip and verify that the time from packing to unpacking of the shipment does not exceed 24 hours.

- The time and date of packing for transport is recorded on the shipping box label, packing slip(s) or INV Form- Inter-Facility Blood, Blood Component and Derivative transfer
 - If time exceeds 24 hours, contact the shipper immediately and quarantine product while investigated. Refer to procedural notes 6.2 and 6.3

4.3 Obtain receipt label; attach to packing slip and complete required documentation on label as performed

- For plasma protein products (derivatives) received by Inter-facility transfer from Non Trace Line sites only complete section B on INV Form- Inter-Facility Blood, Blood Component and Derivative transfer

4.4 Open the shipping containers one at a time and inspect the packing of the plasma protein products (derivatives) inside.

- Appropriate packing configuration will vary depending if received from CBS or DSM site and shipping containers used. Refer to procedural note 6.5
- If packing configuration unsatisfactory; contact the shipper immediately, quarantine the product while investigated. Refer to Procedure note 6.3.

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4.0 Procedure Cont'd

- 4.5** Remove plasma protein products (derivatives) from shipping container and account for all products in the shipment by; verifying lot number and number of vials received against packing slip, or INV Form- Inter-Facility Blood, Blood Component and Derivative transfer:
- If there are any discrepancies, contact the shipper immediately, quarantine the product while investigated. Refer to Procedure note 6.3
- Note:** Place into acceptable monitored storage conditions
- 4.5.1** Stock plasma protein products (derivatives) received at Non- Trace Line sites are shipped from the designated Trace Line testing site or Trace Line hub site for the Non- Trace Line site
- Each vial will have Trace Line generated and DSM 104 tag with RhIG having treatment slip attached with product information.
- 4.5.2** Factor Concentrates, C1 Esterase or SCIG (Hizentra) for Clinical Home Program patients received at Non- Trace Line sites are shipped from the designated Trace Line testing/hub site for the Non- Trace Line site
- Trace Line generated patient specific information is attached to each
 - ROT's will be enclosed for all vials in shipment
 - Verify information on packing slip to ROT's and labels/tags attached
 - If patient requires emergency stock; dose required will be on separate packing slip for rotation with current emergency stock
- 4.6** Perform visual inspection. Refer to INV Procedure- Visual Inspection of Blood, Blood Components and Derivatives.
- If visual inspection unsatisfactory, contact the shipper immediately, quarantine product while investigated. Refer to procedural note 6.3
- 4.7** Confirm all plasma protein products requested were received by verifying against applicable CBS/DSM order form
- 4.7.1** For Factor Concentrates or C1 Esterase received for Home program patients that have emergency stock available at facility rotate stock with new product received
- 4.7.2** For Trace Line sites if applicable reserve vials. Refer to Trace Line procedure: Reserve/Cancel Reservation of Blood, Blood Components and Derivatives in Trace Line
- 4.8** Store plasma protein products at the appropriate storage temperature
- Store plasma protein products by expiration date to ensure that the oldest vials will be selected first
- 4.9** For Non Trace Line sites document all required information in blood bank log from packing slip
- 4.10** For Trace Line proceed to enter in Trace Line. Refer to Trace Line procedures as applicable
- Receipt of Blood, Blood Components and Plasma Protein Products- Derivatives (from CBS) in Trace Line
 - Handling in Trace Line: Receipt of Inter-Facility Shipment of Blood, Blood Components and Derivatives
- 4.11** Retain the Packing slip or INV Form- Inter-Facility Blood, Blood Component and Derivative in appropriate location in blood bank/BTS
- 4.12** For Trace Line sites that received plasma protein products (derivatives) from BPM at CBS; sign, date and fax packing slip to BPM at CBS
- 4.13** With the shipping box proceed to
- Remove any ice packs and store in designated location in freezer (preferably -20°C).
 - Remove shipping labels(s)
 - Store in an appropriate location or return to blood supplier as per established procedure

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5.0 Reporting

- 5.1** Ensure all required documentation is completed on receipt label and/or INV Form- Inter-Facility Blood, Blood Component and Derivative transfer
- 5.2** For Non- Trace Line sites ensure all required receipt information is completed in blood bank log
- 5.3** Ensure appropriate customer feedback form (DSM or CBS) is completed for any shipments with issues
- 5.4** Ensure a DSM Non Conformance in Intelix is completed on any shipments with issues received from a DSM site
- 5.5** For Trace Line sites that received plasma protein products (derivatives) from BPM at CBS; ensure packing slip is signed, dated and faxed to BPM at CBS

6.0 Procedural Notes

- 6.1** If a security seal was not present on the shipping container:
 - If shipped by a public transport system such as Greyhound Bus Lines, airline or taxi, consult Medical Director and then discard the product
 - If shipped by a designated facility transport such as air ambulance, facility driver, family member, the shipper in consult with the receiving facility may consider authorizing release of the product
- 6.2** Product(s) that have been transported in a shipping container longer than 24 hours should be discarded, as proper storage temperature cannot be guaranteed.
- 6.3** If product deemed unsuitable for use by receiving site/ shipper
 - 6.3.1** If product designated for specific patient contact attending physician or nurse practitioner immediately
 - 6.3.2** Document as received
 - 6.3.3** Discard or return to the blood supplier (as appropriate after investigation/consultation)
 - Document reason for discard/return on packing slip/INV Form- Inter-Facility Blood, Blood Component and Derivative transfer and in the appropriate blood bank log Trace Line.

Note: For Trace Line sites refer to appropriate Trace Line Procedure: Handling Discarded/Expired/Recalled Blood, Blood Components and Derivatives in Trace Line
 - 6.3.4** In extenuating circumstances (product irreplaceable/urgent need for product), consult with supervisor for further direction.
 - Acceptance of blood that does not meet receiving requirements must be authorized for use by the BTS Medical Director or designate/TM Physician on call
 - Authorization must be documented on the packing slip or INV Form- Inter-Facility Blood, Blood Component and Derivative transfer and in the appropriate blood bank log.
 - 6.3.5** Complete appropriate customer feedback form and fax to supplier.
 - If received from DSM site complete INV form: DSM Customer Feedback form
 - If received from CBS complete CBS Hospital customer feedback form (Winnipeg) available on CBS website, hospitals, customer service, feedback and survey at: <https://blood.ca/en/hospitals/feedback-and-surveys>
 - 6.3.6** Reorder product from supplier
 - 6.3.7** If received from DSM site complete DSM Non Conformance in Intelix
- 6.4** If plasma protein products (derivatives) were transfused to a patient en route, the transfusion information should be recorded on INV Form- Inter-Facility Blood, Blood Component and Derivative transfer or on Record of Transfusion (ROT) for plasma protein products (derivatives) issued from Trace Line sites.
 - If the plasma protein products (derivatives) were documented as sent but not received and disposition was not recorded INV Form- Inter-Facility Blood, Blood Component and Derivative transfer or on Record of Transfusion (ROT); then an investigation must be done to determine if the units were transfused

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6.0 Procedural Notes Cont'd

- 6.5** Appropriate packing configuration varies and is dependent if product received from CBS or DSM site and shipping containers used
- For plasma protein products received from CBS in a regular blood box; if product requires refrigeration, one ice pack will be used and if product can be stored at room temperature, no ice packs will be used
 - For acceptable packing configuration for product received from DSM sites refer to INV Procedure: Inter-Facility shipping of Blood, Blood Components and Plasma Protein Products (Derivatives)
 - For CBS packing configuration. Refer to CBS customer letter 2017-03 at :
<https://blood.ca/en/hospital/customer-letters>